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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,390	01/22/2004	Koral Embil	EDKO-001	2411
7590		04/09/2007		
Louis C. Paul 9th Floor 730 Fifth Avenue New York, NY 10019			EXAMINER CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT 1615	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
3 MONTHS			04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/761,390

Applicant(s)

EMBIL ET AL.

Examiner

Lakshmi S. Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4-28-04;7-21-04</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Receipt of IDS dated 4-28-04 and 7-21-04 is acknowledged.

Claims 1-28 are pending in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1, 2, 4-7 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,106,812 to Prencipe et al (Prencipe) OR

Claims 1, 2, 4-7 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/15726 (submitted on PTO-1449, hereafter WO 26).

Prencipe teaches a dual compartment tooth whitening (reads on instant cosmetic) composition comprising a first ingredient and a second ingredient in different compartments. The first ingredient is a peroxide compound and the second ingredient includes an antibacterial or an anti-tartar or abrasive compound (abstract, col. 4, L 37-67). The components are kept separate until dispensed. Further Table 1 shows the composition of both compositions, which shows the presence of water and also a polymer in one of the compositions and thus meet the claimed limitations (claim 1). With respect to the claimed "substantially same lipophilicity", instant specification does not set any specific amount of lipophilicity.

WO 26 teaches a composition for acne treatment comprising clindamycin and benzoyl peroxide in the form of a kit, separately maintained in different containers (page 9, L 25-35 and Example compositions on pages 11-12). Benzoyl peroxide composition comprises a polymer and both compositions have water and hence meet the claimed limitations.

While, neither Prencipe nor WO 26 state the lipophilicity exclusively, the compositions of two components (table 1) are both water based and do not appear to vary in their hydrophilicity or lipophilicity. Both teach adjusting the viscosity of the compositions for better release and activity. Accordingly, absent evidence of unexpected advantage with a composition that is commensurate with the scope of the claims, it would have been obvious for an ordinary skill in the art at the time of the instant invention was made to choose the formulations of Prencipe or WO so as to

maintain the solubility or homogeneity of the compositions so as to be able to dispense and retain the activity desired.

2. Claims 4 and 8-22 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/15726 (submitted on PTO-1449, hereafter WO 26) as applied to claims 1, 2 and 4-7 above, and further in view of Wester et al (hereafter Wester, J. American Academy of Dermatology) and EP 306236 (hereafter EP), both submitted on PTO-1449.

WO 26 described above, fails to teach the claimed microsphere polymer of the instant claims. WO also fails to teach the combination of active agents other than benzoyl peroxide and clindamycin.

Wester teaches controlled release of benzoyl peroxide from a porous microsphere polymeric system for reducing topical irritancy. Wester compared the difference between the release of the above compound from a polymeric composition and non-polymeric composition (freely dispersed drug) and observed that the compound of significantly better absorbed through the skin when released from the former system and also reduced irritation (abstract, lines bridging pages 720-721 and results on page 722-723). The polymeric system of Wester is the same as the instant microsphere.

EP also teaches controlled release of several skin care and hair care active agents such as benzoyl peroxide, salicylic acid, minoxidil etc., from a composition containing a microsphere polymeric system (the same microsphere as that claimed in

Art Unit: 1615

the instant invention). In particular, EP (as well as Wester) teaches the treatment of acne with benzoyl peroxide. For the various active agents of EP, see pages 2-5, 7, page 12, L 40-45 and examples and on page EP teaches a number of combinations of the active agents.

Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ the microsphere polymeric delivery material of Wester or EP as a polymer in the composition of WO26, either in one or both compartments, because both Wester and EP suggests that the porous polymeric material forms a continuous network open to the exterior particles, permitting outward diffusion of the impregnated active agents in a controlled fashion. Further, EP suggests that the polymer is suitable for a wide variety of active agents and their combinations and hence including any combination of active agents, in the teachings of WO26, that are suitable for acne treatment would have been obvious for a skilled artisan. Further, incorporating more than two active agents in different dispensing containers (in the teachings of WO26), and adjusting the openings or closures, so that the active agents can be dispensed separately would have been obvious from the teachings of EP because EP suggests more than two active ingredients for the same treatment such as acne.

Specification

The use of a number of trademark compounds has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic

terminology. Examiner notes that the compounds are appropriately designated as trademark, but does not have generic names.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5,510, 116 to Froix et al teaches particulate polymers, such as claimed Microsponge, for releasing active agents from a pressurized container.

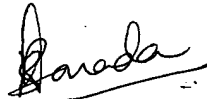
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615
March 31, 2007



LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER